



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2006

Boston Scientific Corporation
% Ms. Angela Byland
Manager, Regulatory Affairs
Cardiovascular
Two Scimed Place
Maple Grove, Minnesota 55311

Re: K012883

Trade/Device Name: Ultraflex Stent Systems (i.e., Ultraflex Esophageal Stent System, Ultraflex Diamond Biliary Stent System, and Ultraflex Tracheobronchial Stent System)

Regulation Number: 21 CFR 878.3610, 21 CFR 876.5010, and 21 CFR 878.3720

Regulation Name: Prosthesis, tracheal, expandable

Regulatory Class: II

Product Code: ESW, FGE, and JCT

Dated: October 1, 2001

Received: October 2, 2001

Dear Ms. Byland:

This letter corrects our substantially equivalent letter of October 12, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

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CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Devices

Indications for Use

510(k) Number (if known): K012883

Device Name: Ultraflex Diamond Biliary Stent

Indications For Use:

The Ultraflex Diamond Biliary Stent is indicated for palliative treatment of patients with malignant biliary strictures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Julie L. Lewis
(Division Sign-Off)

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and Neurological Devices Page 1 of _____

510(k) Number K012883

Indications for Use

510(k) Number (if known): K012883

Device Name: Ultraflex Esophageal Stent System

Indications For Use:

The Ultraflex Esophageal Stent System is indicated for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Juli L. Lewis
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices Page 1 of _____

510(k) Number K012883

Indications for Use

510(k) Number (if known): K012883

Device Name: Ultraflex™ Tracheobronchial Stent System

Indications for Use:

The Ultraflex Tracheobronchial Stent System is indicated for treatment of tracheobronchial strictures produced by malignant neoplasms.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K012883

Boston Scientific

510(K) SUMMARY K012883

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01545
Telephone: 508-683-4942
Fax: 508-683-5939

Contact: Kathleen Morahan
Director Regulatory Affairs
Original Date Prepared: August 6, 2001
Revision Date: July 14, 2006

2. Device:

Trade Name: Ultraflex™ Esophageal Stent System
Common Name: Esophageal Prosthesis
Classification Name: Esophageal Prosthesis
Regulation Number: 878.3610
Product Code: ESW
Classification: Class II

Trade Name: Ultraflex™ Diamond Biliary Stent System
Common Name: Biliary Stent
Classification Name: Biliary Catheter and Accessories
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

Trade Name: Ultraflex™ Tracheobronchial Stent System
Common Name: Tracheal Prosthesis
Classification Name: Tracheal Prosthesis
Regulation Number: 878.3720
Product Code: JCT
Classification: Class II

3. Predicate Device:

Boston Scientific Corporation's Ultraflex™ Esophageal Stent System, K940838
Boston Scientific Corporation's Ultraflex™ Diamond Biliary Stent System, K962899
Boston Scientific Corporation's Ultraflex™ Tracheobronchial Stent System, K963241

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Boston Scientific

4. Device Description:

The proposed Esophageal, Biliary and Tracheobronchial Ultraflex stents are comprised of two components, a metallic expandable stent and a flexible delivery catheter. The stents are mounted on a delivery catheter. The delivery catheter is placed over a guidewire and through the working channel of an endoscope to deliver the stent. The stents are available in a variety of diameters and lengths.

5. Intended Use:

The proposed Ultraflex Esophageal Stent System is intended for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.

The proposed Ultraflex Diamond Biliary Stent System is indicated for palliative treatment of patients with malignant biliary strictures.

The proposed Ultraflex Tracheobronchial Stent System is intended for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

6. Technological Characteristics:

There are no differences in the technological characteristics between the proposed and predicate devices. The purpose of this Special 510(k) is to request a labeling claim that the Ultraflex stents are MRI safe and MRI compatible.

7. Performance Data:

Bench testing was conducted to support the MRI safety and compatibility claim.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed Esophageal, Biliary and Tracheobronchial Ultraflex stents are substantially equivalent to Boston Scientific Corporation's currently marketed Esophageal, Biliary and Tracheobronchial Ultraflex stents.